

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION

AMNIOTIC THERAPIES, LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 3:16-cv-2412-K
	§	
U.S. FOOD AND DRUG	§	
ADMINISTRATION,	§	
	§	
Defendant.	§	

**ORDER**

Before the Court is Plaintiff Amniotic Therapies, LLC’s Emergency Motion for Temporary Restraining Order and Request for Immediate Hearing (“Emergency Motion”) to enjoin and stay an order issued by Defendant United States Food and Drug Administration (“FDA”) (Doc. No. 2). An order issued by the FDA on August 16, 2016 (“FDA Order”), required Plaintiff to recall, destroy, and cease manufacturing certain products. The FDA Order prompted Plaintiff to file the Emergency Motion at issue here. The Court has reviewed the Motion, the materials submitted by Plaintiff, and the applicable law and finds that the motion should be **GRANTED**. Accordingly, and pursuant to Federal Rule of Civil Procedure 65(b), for the reasons detailed below, the Court finds it necessary to grant this Order without notice.

It is therefore **ORDERED** that:

(1) Defendant is stayed from compelling Plaintiff to cease manufacturing.

- (2) Defendant is stayed from compelling Plaintiff to issue a recall on its products.
- (3) Plaintiff must cease distribution of all of its product subject to the FDA Order.
- (4) The Court will revisit the merits of this Motion at a hearing that is scheduled to be held on August 31, 2016 at 1:30 p.m., in Judge Kinkeade's Courtroom in the Earle Cabell Federal Building, located at 1100 Commerce St., Dallas, Texas 75242. Each side will be limited to thirty minutes of oral argument.

This temporary restraining order will take effect when Plaintiff posts with the Clerk of the Court the cash sum of \$1,000, or a bond in that amount in a form, and with a surety, approved by the Clerk of the Court.

#### **I. Legal Standard**

To be entitled to a temporary restraining order, a plaintiff must demonstrate it meets a four-prong test. Plaintiff must demonstrate: (1) a substantial likelihood of success on the merits; (2) a substantial threat of immediate and irreparable harm for which it has no adequate remedy at law; (3) that greater injury will result from denying the temporary restraining order than from its being granted, and; (4) that a temporary restraining order will not disserve the public interest. *Clark v. Prichard*, 812 F.2d 991, 993 (5th Cir. 1987). If a party fails to meet any of the four requirements, the Court cannot grant the temporary restraining order.

A temporary restraining order should only be granted if the movant clearly carried the burden of persuasion on all four requirements. *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985). The Court finds that Plaintiff has established each of the four required elements here.

## **II. Analysis**

Plaintiff manufactures, stores, labels, and distributes amniotic based wound care products. Plaintiff began manufacturing and distributing products in September 2014. Since Plaintiff began production, four reports have been made by patients that used Plaintiff's products that a product produced by Plaintiff possibly caused each of the patients to contract an infection after they received treatment at St. Vincent's Hospital in Cleveland, Ohio. Each of the reported incidents occurred between August 2015 and October 2015. The four patient reports are the only instances in which Plaintiff's products were considered the possible cause of infection for a patient.

After the patients made the reports, Defendant FDA conducted two different inspections of Plaintiff's manufacturing facility. An inspection by Defendant on May 4, 2016 concluded that conditions in Plaintiff's facility were in violation of FDA regulations and did not provide protection against the risks of communicable disease transmission and there was reasonable grounds to believe that certain products of Plaintiff posed a danger to human health. As a result of the inspection, on August 16, 2016, Defendant issued the FDA Order that required Plaintiff to recall, destroy, and cease all manufacturing immediately of certain products because the FDA

concluded that it had reasonable grounds to believe that certain products posed a danger to health. The FDA Order required that Plaintiff comply with the recall of products and destruction of inventory by August 23, 2016.

Plaintiff then filed the Emergency Motion at issue on August 19, 2016. Because the FDA Order required that Plaintiff to cease manufacturing, recall products, and destroy inventory, Plaintiff believes that compliance with the FDA Order will inevitably cause substantial harm to Plaintiff's business.

**A. Substantial Likelihood of Success on the Merits**

The Court finds that Petitioner has shown a substantial likelihood of success on the merits. The facts in Plaintiff's Emergency Motion demonstrate that the FDA Order likely falls short of the necessary requirements to require Plaintiff to cease manufacturing, recall products, and destroy inventory. The Public Health Service Act, codified at 42 U.S.C. § 264, only allows an order to command destruction of products when the products at issue are "found to be so infected or contaminated as to be sources of dangerous infection to human beings . . . ." Here, the FDA Order was based on Defendant's conclusion that there were "reasonable grounds to believe" that products manufactured by Plaintiff pose a danger to health rather than an actual finding that Plaintiff's products in fact pose a danger to health. Therefore, this requirement is satisfied since there is a substantial likelihood of success on the merits for Plaintiff.

**B. Irreparable Injury**

This Court also finds that emergency relief is necessary to prevent irreparable injury to Plaintiff. There must be a substantial threat that irreparable harm will result if the emergency motion is not granted. *Clark*, 812 F.2d at 993. Here, if Plaintiff is required to recall all products in compliance with the FDA Order then it would result in reputational harm to Plaintiff that would cause a significant impairment in Plaintiff being able to retain business in the future. The Plaintiff would also suffer financial harm by having to destroy its current inventory in compliance with the FDA Order, which Plaintiff estimates is valued at approximately \$359,000.00. This requirement to grant the Emergency Motion is satisfied because denying the Emergency Motion will result in irreparable injury to Plaintiff.

**C. Weighing the Balance of Injury to the Parties**

The Court also finds that greater injury will result from denial of the Emergency Motion than from granting the Emergency Motion. Here, if the temporary restraining order is denied then it could result in Plaintiff losing significant amounts of revenue and laying off three of its five employees. On the other hand, if the temporary restraining order were granted then the inevitable financial harm that would occur to Plaintiff's business would not occur. Therefore, there is greater injury that will result from the denial of the Emergency Motion.

**D. Public Interest**

The Court also finds that Plaintiff has demonstrated that the public interest will be served by granting the Emergency Motion. If the temporary restraining order is not granted it is unlikely that Plaintiff would have the opportunity to challenge any of the findings that Defendant based the FDA Order on. There also have been no other reports of infections from Plaintiff's products other than from the four patients from August 2015 to October 2015 at St. Vincent Hospital so there is not a risk to the public. Notably, once Plaintiff was notified of the four patient infections it recalled the lot of products associated with the specific patient reports. Therefore, the public interest will be served by granting the Emergency Motion because it would allow Plaintiff and other similarly situated businesses to challenge the information underlying government injunctions.

### **III. Conclusion**

For the foregoing reasons the Court grants Plaintiff's Emergency Motion for Temporary Order and Request for Immediate Hearing.

**SO ORDERED.**

Signed August 19<sup>th</sup>, 2016.

  
ED KINKEADE  
UNITED STATES DISTRICT JUDGE